IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Christine L. Brakel et al.

Serial No. 08/479,999) Group Art Unit: 1631

Filed: June 28, 1994) Ex'r: Ardin H. Marschel, Ph.D.

Title: MODIFIED NUCLEOTIDE COMPOUNDS)

(As Previously Amended) 527 Madison Avenue, 9th Floor

New York, NY 10022-4304

December 15, 2003

FILED BY EXPRESS MAIL

Mail Stop Petitions Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 RECEIVED DEC 1 5 2003

OFFICE OF PETITIONS

REQUEST FOR RECONSIDERATION OF APPLICANTS DECEMBER 26, 2001 PETITION UNDER 37 C.F.R. §1.137(b)

Dear Sirs:

In response to the Decision mailed on October 14, 2003 (copy attached as Exhibit A), Applicants respectfully request reconsideration of their December 26, 2001 Petition Under 37 C.F.R. §1.137(b) to Revive an Unintentionally Abandoned Application. A response to the October 14, 2003 Decision was originally due on December 14, 2003. Because December 14, 2003 falls on a Sunday, under 37 CFR 1.7, a response filed on the next succeeding day which is not a Saturday, Sunday or a federal holiday, is considered timely filed. Accordingly, this response is being timely filed.

Christine L. Brakel et al. Serial No. 08/479,999 Filed: June 28, 1994

Page 2 (Request for Reconsideration of Applicant December 26, 2001 Petition Under 37 C.F.R. §1.137(b) - December 15, 2003)

EXPRESS MAIL CERTIFICATE

"Express Mail" Label No. EL1905579881US

Deposit Date

December 15, 2003

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington DC 20231.

Ronald C. Fedus

Date

Reg. No. 32,567

Filed: June 28, 1994

Page 3 (Request for Reconsideration of Applicant December 26, 2001 Petition Under 37 C.F.R. §1.137(b) - December 15, 2003)

In the October 14, 2003 Decision, the Petitions Examiner stated:

Petitioner's only submission, an amendment, has been determined by the examiner not to prima facie place the application in condition for allowance. Thus, petitioner has failed to submit the required reply.

In response Applicants respectfully point out that their filing on December 26, 2001 included as Exhibit 4 a Notice of Appeal. For the Petition Examiner's review, a complete copy of Applicants December 26, 2001 filing, including the Notice of Appeal (Exhibit 4), is attached as Exhibit B.

No fee or fees are believed due in connection with this response. In the event that any fee or fees are due, however, The United States Patent and Trademark Office is hereby authorized to charge any such fee(s) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

A duplicate copy of this Request for Reconsideration (but without attached Exhibits A and B) is also submitted herewith.

Favorable action on this Request for Reconsideration is respectfully requested.

Respectfully submitted,

Ronald C. Pedus

Registration No. 32,567 Attorney for Applicants

ENZO THERAPEUTICS, INC. c/o Enzo Biochem, Inc. 527 Madison Avenue (9th Fl.) New York, New York 10022 Telephone: (212) 583-0100 Fax: (212) 583-0150



COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
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Paper No. 50

ENZO BIOCHEM INC 527 MADISON AVENUE (9TH FLOOR) NEW YORK NY 10022 CHARLE THE CO

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OFFICE OF PETITIONS

In re Application of Brakel, et al. Application No. 08/479,999 Filed: June 28, 1994 Title: MODIFIED NUCLEOTIDE COMPOUNDS

DECISION ON PETITION

This is a decision on the petition to revive the above-identified application under 37 CFR 1.137(b), filed December 26, 2001. The Office apologizes for the delay.

The petition is DISMISSED.

Any request for reconsideration of this decision must be submitted within TWO (2) MONTHS from the mail date of this decision. Extensions of time under 37 CFR 1.136(a) are permitted. The reconsideration request should include a cover letter entitled "Renewed Petition Under 37 CFR 1.137(b)." This is **not** a final agency decision within the meaning of 5 USC 704.

The above-identified application became abandoned for failure to timely file a proper response to the final Office action mailed September 26, 2000, which set a shortened statutory period for reply of three months. No extensions of time under the provisions of 37 CFR 1.136(a) were obtained. Accordingly, the above-identified application became abandoned on December 27, 2000. A Notice of Abandonment was mailed on July 16, 2001.

A grantable petition under 37 CFR 1.137(b) must be accompanied by: (1) the required reply, unless previously filed; (2) the petition fee as set forth in 37 CFR 1.17(m); (3) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 CFR 1.137(b) was unintentional; and (4) any terminal disclaimer (and fee as set forth in 37 CFR 1.20(d)) required by 37 CFR 1.137(d).

The instant petition lacks item (1), the required reply.

With the instant petition, petitioner filed an amendment in response to the final Office action. The proposed reply to a final Office action required for consideration of a petition to revive must be either (1) a Notice of Appeal (and fee required by law); (2) an amendment that prima facie places the application in condition for allowance; (3) the filing of a continuing application under 37 CFR 1.53(b) or if applicable, 1.53(d); (4) a request for a continuing examination (RCE) under 37 CFR 1.114; or (5) if applicable, a 37 CFR 1.129(a) submission.

Petitioner's only submission, an amendment, has been determined by the examiner not to *prima facie* place the application in condition for allowance. Thus, petitioner has failed to submit the required reply.

In order for the application to be revived, petitioner must submit a required reply within the meaning of 37 CFR 1.137(b)(1). Any renewed petition should be accompanied by a proper reply in the form of a Notice of Appeal, the filing of a continuation application or an RCE. If petitioner fails to reply in the form of a Notice of Appeal, a proper continuing application, or a proper RCE, it may be construed as an intentional delay in presenting a grantable petition, which may adversely affect petitioner's ability to revive the abandoned application.

The \$1,280 fee for the petition under 37 CFR 1.137(b) has been charged to Deposit Account No. 05-1135, as authorized.

Further correspondence with respect to this matter should be addressed as follows:

By mail:

Assistant Commissioner for Patents

Box DAC

Washington, D.C. 20231

By FAX:

(703) 308-6916

Attn: Office of Petitions

By hand:

Crystal Plaza Four, Suite 3C23

2201 S. Clark Place Arlington, Virginia

Telephone inquiries concerning this decision should be directed to the undersigned at (703) 305-0272.

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Cliff Congo Petitions Attorney Office of Petitions

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Christine L. Brakel et al.

Serial No. 08/479,999 Group Art Unit: 1631

Filed:

June 28, 1994

Ex'r: Ardin H. Marschel, Ph.D.

MODIFIED NUCLEOTIDE COMPOUNDS

(As Previously Amended

527 Madison Avenue, 9th Floor New York, New York 10022 December 26, 2001

FILED BY EXPRESS MAIL

Commissioner of Patents and Trademarks* Washington, D.C. 20231 **Box DAC**

Attention:

Office of Deputy Assistant Commissioner for Patents

2121 Crystal Drive -- Crystal Park 2 - Suite 913

Arlington, Virginia 22202

PETITION UNDER 37 C.F.R. §1.137(b) TO REVIVE AN UNINTENTIONALLY ABANDONED APPLICATION

Dear Sirs:

Applicants submit this Petition to the Commissioner under the provisions of 37 C.F.R. §1.137(b) to revive the above-identified application in which taking

EXPRESS MAIL CERTIFICATE

"Express Mail" Label No. EL491424303US

Deposit Date

December 26, 2001

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington DC 20231.

Ronald C. Fedus

C 26 2001

Reg. No. 32,567

^{*} In accordance with the November 16, 2001 Notification Related to United States Postal Service Interruption, this paper and all attachments are being sent by Express Mail to: U.S. Patent and Trademark Office, P. O. Box 2327, Arlington, VA 22202. See Suspension of the "Express Mail" Service of United States Postal Service for mail addressed to ZIP Codes 202xx through 205xx.

Filed: June 28, 1994

Page 2 (Petition Under 37 C.F.R. §1.137(b) To Revive An Unintentionally Abandoned Application - December 26, 2001)

action was unintentionally delayed. A response to the September 26, 2000 Office Action issued in this application was originally due on December 26, 2000. Upon the expected granting of this Petition, this application will be revive and the accompanying response in the form of an Amendment Under 37 C.F.R. §1.116 will be considered as having been timely filed.

The above-identified application became unintentionally abandoned after December 26, 2000, which was the date that a response to the September 26, 2000 Office Action was originally due. A Notice of Abandonment was subsequently mailed on July 16, 2001. A copy of the July 16, 2001 Notice of Abandonment is attached to this Petition as Exhibit 1. A Terminal Disclaimer To Accompany Petition is also attached to this paper as Exhibit 2.

It is hereby requested that this application be revived because the entire delay in filing the response to the September 26, 2000 Office Action until the filing of this Petition was unintentional. As indicated above, a response to the September 26, 2000 Office Action in the form of an Amendment Under 37 C.F.R. §1.116 is being submitted concurrently herewith and is attached as Exhibit 3. A Notice of Appeal is also attached to this paper as Exhibit 4.

The fee for filing a Petition to Revive an Unintentionally Abandoned Application Under 37 C.F.R. §1.137(b) is \$1,280.00 for a large entity. The Patent and Trademark Office is hereby authorized to charge Deposit Account No. 05-1135 for the requisite large entity fee of \$1,280.00. The Patent and Trademark Office is further authorized hereby to charge Deposit Account No. 05-1135 for any other fees required in connection with this Petition and the attached Amendment, or to credit any overpayment thereto.

A duplicate copy of this Petition but without attached Exhibits 1-4 is also submitted herewith.

Christine L. Brakel et al. Serial No. 08/479,999 Filed: June 28, 1994

Page 3 (Petition Under 37 C.F.R. §1.137(b) To Revive An Unintentionally Abandoned Application - December 26, 2001)

Favorable action on this Petition is earnestly solicited.

Respectfully submitted,

Ronald C. Fedus

Registration No. 32,567 Attorney for Applicants

ENZO THERAPEUTICS, INC. c/o Enzo Biochem, Inc. 527 Madison Avenue (9th Fl.) New York, New York 10022 Telephone: (212) 583-0100 Fax: (212) 583-0150



UNITED STATE EPARTMENT OF COMMERCE United States Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTO	RNEY DOCKET NO.
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Notice of Abandonment

Application No. 08/479,999

Ardin Marschel

Examiner

Applicant(s)

Art Unit 1631

Brakel et al.

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address

Th	iis a	ppl	ication is abandoned in view of:
1.	X	A	oplicant's failure to timely file a proper reply to the Office letter mailed on <u>Sep 26, 2000</u> .
	(a)		A reply was received on (with a Certificate of Mailing or Transmission dated), which is after the expiration of the period for reply (including a total extension of time of month(s)) which expired on
			month(s)) which expired on
	(b)		A proposed reply was received on, but it does not constitute a proper reply under 37 CFR 1.113(a) to the final rejection.
		àp	proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the plication in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for intinued Examination (RCE) in compliance with 37 CFR 1.114).
	(c)	X	No response has been received.
2.		· Al	oplicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of ree months from the mailing date of the Notice of Allowance (PTOL-85).
	(a)		The issue fee and publication fee, if applicable, was received on (with a Certificate of Mailing or Transmission dated), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance.
	(b)		The submitted issue fee of \$ is insufficient. A balance of \$ is due.
	•		The issue fee required by 37 CFR 1.18 is \$ The publication fee, if required by 37 CFR 1.18(d) is \$
	(c)		The issue fee and publication fee, if applicable, has not been received.
3.			oplicant's failure to timely file new formal drawings as required by, and within the three-month period set in, the Notice Allowability (PTO-37).
	(a)		Proposed new formal drawings were received on (with a Certificate of Mailing or Transmission dated), which is after the expiration of the period for reply.
	(b)		The proposed new formal drawings filed on are not acceptable and the period for reply has expired.
	(c)		No proposed new formal drawings have been received.
4.			ne letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire terest, or all of the applicants.
5.			ne letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under CFR 1.34(a)) upon the filing of a continuing application.
3.			ne decision by the Board of Patent Appeals and Interferences rendered on and because the eriod for seeking court review of the decision has expired and there are no allowed claims.
7.		Tř	ne reason(s) below: Ardin I Marsel ARDIN H. MARSCHEL PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier) 6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson. MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in ABANDONMENT of the application

1

PTO/SB/63 (10-00)
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TERMINAL DISCLAIMER TO ACCOMPANY PETITION	Docket Number (Optional)
In re Application of: Christine L. Brakel et al.	
Name:	
Application Number: 08/479,999	
Filed: June 28, 1994	
For: Modified Nucleotide Compounds	
The owner*,	period of abandonment of the above- or plant application, the lesser of: (a) peyond twenty years from the date on if the application contains a specific 365(c), from the date on which the patent granted on a utility or plant of the above- ntains a specific reference under 35
Check either box 1 or 2 below, if appropriate.	
1. For submissions on behalf of an organization (e.g., corporation, p agency, etc.), the undersigned is empowered to act on behalf of the	
2. The undersigned is an attorney or agent of record.	
Signature	
Ronald C. Fe	edus
Reg. No. 32, Terminal disclaimer fee under 37 CFR 1.20(d) included. X The Patent and Trademark Office is hereby authorized to cha WARNING: Information on this form may become public. Cred included on this form. Provide credit card information and aut the Terminal Disclaimer fee under 37 C.F.R. 1.20(d) and for any Statement under 37 CFR 3.73(b) is required if terminal disclaimer is sign	rge Deposit Account No. 05-1135 for **it card information should not be horization on PTO-2038. other required fees. ed by the assignee (owner).
* Statement under 37 CFR 3.73(b) is required if terminal disclaimer is sign Form PTO/SB/96 may be used for making this certification. See MPEP	other required fees. led by the assignee (owner). § 324.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

. . .

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

Christine L. Brakel et al.

Serial No.

08/479,999

Group Art Unit: 1631

Filed:

June 28, 1994

Ex'r: Ardin H. Marschel, Ph.D.

Title:

MODIFIED NUCLEOTIDE COMPOUNDS (As Previously Presented)

FILED VIA EXPRESS MAIL

Honorable Commissioner of Patents and Trademarks Washington, D. C. 20231

Sir:

Transmitted herewith is an Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) in the above-identified patent application.

The fee* has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
Total	51	Minus	52	=0	X \$9	\$ 0.00
Indep	5	Minus	6	=0	X \$42	\$ 0.00
()	First Presentation of Multiple Dependent Claims				\$ 140	\$ 0.00
	TOTAL ADDITIONAL FEE		·			\$ 0.00

^{*}Small entity status was previously established in this application and is still applicable.

()	Charge Deposit Account No. 05-110	35 in the amount of \$
()	A check in the amount of \$	is attached.

(X) The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 05-1135 any filing fees under 37 C.F.R. §1.16 for the presentation of extra claims and any patent application processing fees under 37 C.F.R. §1.17.

Copies are being provided in triplicate.

Christine L. Brakel et al. Serial No.: 08/479,999 Filed: June 28, 1994

Page 2 (Transmittal -- December 26, 2001)

EXPRESS MAIL CERTIFICATE

"Express Mail" Label No. EL491424303US

Deposit Date

December 26, 2001

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington DC 20231.

DCC 26 2001

Ronald C. Fedus Reg. No. 32,567

Filed: June 28, 1994

Page 3 (Transmittal -- December 26, 2001)

Also enclosed: Petition Under 37 C.F.R. §1.137(b) & Notice of Appeal.

December 26, 2001 Date

ENZO THERAPEUTICS, INC. c/o Enzo Biochem, Inc. 527 Madison Avenue (9th Fl.) New York, New York 10022 Tel. (212) 583-0100

Attorney's Docket No.: Enz-47(C2)

Ronald C. Fedus
Registration No. 32,567
Attorney for Applicant(s)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Christine L. Brakel et al.

Serial No. 08/479,999

Group Art Unit: 1631

Filed:

June 28, 1994

Ex'r: Ardin H. Marschel, Ph.D.

Title:

MODIFIED NUCLEOTIDE COMPOUNDS)

(As Previously Presented)

527 Madison Avenue, 9th Floor New York, New York 10022 December 26, 2001

FILED VIA EXPRESS MAIL

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

AMENDMENT UNDER 37 C.F.R. §1.116 (IN RESPONSE TO THE SEPTEMBER 26, 2000 OFFICE ACTION)

Dear Sirs:

Please enter this response (Amendment Under 37 C.F.R. §1.116) to the Office Action mailed on September 26, 2000 in connection with the above-identified application. A response to the September 26, 2000 Office Action was originally due by December 26, 2000. This response is accompanied by a Petition Under 37 C.F.R. §1.137(b) and authorization for the fee therefor. Accordingly, upon granting of Applicants' Petition, this response (Amendment) will be considered as having been being timely filed.

Filed: June 28, 1994

Page 2 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

EXPRESS MAIL CERTIFICATE

"Express Mail" Label No. EL491424303US

Deposit Date

December 26, 2001

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington DC 20231.

Ronald C. Fedus

DEL Z6 2001

Reg. No. 32,567

Date



Christine L. Brakel et al. Serial No. 08/479,999 Filed: June 28, 1994

Page 3 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

KINDLY AMEND THIS APPLICATION AS FOLLOWS:

In The Title:

Please substitute the following title of the invention:

-- MODIFIED RNase H NUCLEOTIDE COMPOUNDS -- .

In the Claims:

Please enter replacement claims 1, 18, 19, 21, 37, 41 and 51 as follows:

Clean Version of Replacement Claims

1. (Four Times Amended) A modified RNase H resistant nucleotide compound which includes at least one component selected from the group consisting of MN₃M, B(N)_xM and M(N)_xB wherein

N is a phosphodiester-linked modified or unmodified 2'-deoxynucleoside moiety; provided that at least one N is a phosphodiester-linked unmodified 2'-deoxynucleoside moiety;

M is a moiety that confers endonuclease resistance on said component and that contains at least one modified or unmodified nucleic acid base;

B is a moiety that confers exonuclease resistance to the terminus to which it is attached; and

x is an integer of at least 2.

Filed: June 28, 1994

Page 4 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

- 18. (Twice Amended) The modified nucleotide compound of claim 1 which includes at least one sequence of the formula M(N)_xB wherein B is modified or unmodified 2',3'-dideoxyribose nucleotide.
- 19. (Twice Amended) The modified nucleotide compound of claim 1 wherein x is an integer selected from the group consisting of 2 or 2.
- 21. (Four Times Amended) A method of inhibiting the function of an RNA, which comprises:

contacting said RNA, under conditions permissive of hybridization, with a modified RNase H resistant nucleotide compound which includes at least one complementary component selected from the group consisting of MN₃M, B(N)_xM and M(N)_xB wherein:

N is a phosphodiester-linked modified or unmodified 2'-deoxynucleoside moiety; provided that at least one N is a phosphodiester-linked unmodified 2'-deoxynucleoside moiety;

M is a moiety that confers endonuclease resistance on said component and that contains at least one modified or unmodified nucleic acid base;

B is a moiety that confers exonuclease resistance to the terminus to which it is attached; and

x is an integer of at least 2.

37. (Twice Amended) The method of claim 21 wherein the RNA is contacted with a compound which includes at least one sequence of the formula M(N)_xB wherein B is modified or unmodified 2',3'-dideoxyribose nucleotide.

Filed: June 28, 1994

Page 5 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

41. (Twice Amended) A method of treating a human or animal so as to inhibit the function of a target RNA therein which method comprises administering a therapeutically effective amount of a modified nucleotide compound so as to inhibit the function of the target RNA, which modified RNase H resistant nucleotide compound includes at least one component selected from the group consisting of MN₃M, B(N)_xM and M(N)_xB wherein:

N is a phosphodiester-linked modified or unmodified 2'-deoxynucleoside moiety; provided that at least one N is a phosphodiester-linked unmodified 2'-deoxynucleoside moiety;

M is a moiety that confers endonuclease resistance on said component and that contains at least one modified or unmodified nucleic acid base;

B is a moiety that confers exonuclease resistance to the terminus to which it is attached; and

x is an integer of at least 2.

51. (Twice Amended) A modified nucleotide compound which comprises at least one component selected from the group consisting of MN₃M, B(N)_xM and M(N)_xB wherein:

N is a phosphodiester-linked modified or unmodified 2'-deoxynucleoside moiety; provided that at least one N is a phosphodiester-linked unmodified 2'-deoxynucleoside moiety;

M is a moiety that confers endonuclease resistance on said component and that contains at least one modified or unmodified nucleic acid base;

B is a moiety that confers exonuclease resistance to the terminus to which it is attached; and

x is an integer of at least 2.

Christine L. Brakel et al.
Serial No. 08/479,999
Filed: June 28, 1994
Page 6 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

Cancel claim 52.

Filed: June 28, 1994

Page 7 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

REMARKS

Reconsideration of this application is respectfully requested.

Claims 1-52 were previously pending. Replacement claims 1, 18, 19, 21, 37, 41 and 51 have been entered above. Claim 52 has been canceled. No claim has been added by this paper. Accordingly, claims 1-51 as amended hereinabove are presented for further examination on the merits.

Acknowledgement is made that the art unit designated for this application has been changed. Any and all future correspondence will henceforth be directed to Group Art Unit 1631.

In a sincere effort to define their invention more clearly and to narrow the issues on appeal or place claims in an allowable condition, Applicants have amended the claims above. The amendments have restored the originally claimed subject matter in the form of components selected from the group consisting of MN₃M, B(N)_xM and M(N)_xB. Moreover, in amending the claims above, Applicants have also expunged the subject matter deemed new matter in the outstanding September 26, 2001 Office Action. The instantly recited components are supported variously in the specification, including the originally filed claims.

In addition, Applicants are also now covering those compositions as defined in the present claims which are modified *RNase H resistant* nucleotide compounds. The language "RNase H resistant" is also variously supported by Applicants' original disclosure.

Entry of the above amendments to the claims is believed to be appropriate and necessary. First, these amendments do not raise new issues that would require further consideration and/or search by the Examiner. In particular, the amendments to the independent claims (1, 21, 41 and 51) with respect to the

Filed: June 28, 1994

Page 8 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

component(s) recited in Applicants' claimed modified RNase H resistant nucleotide compounds, serve to advance prosecution by addressing an issue or issues raised in the September 26, 2000 Office Action. Further, no issue of new matter is raised by the entry of these amendments, since the subject matter corresponds to the original disclosure, including the originally filed claims. Moreover, it is believed that the amendments will actually serve to place this application in better form for appeal by materially reducing or simplifying the issues for appeal. Finally, the amendments do not present additional claims; instead at least one claim (52) has been canceled in a sincere effort to advance prosecution. Entry of the above amendments to the claims is respectfully requested.

The Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1-19, 21-39, 41, 51, and 52¹ stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the Office Action (pages 2-3), the Examiner stated:

The instant claims have been amended to now contain NEW MATTER. For example, claim 1 now recites several new components made up of various N, M, and B moieties. These arrangements of said components in line 3 of claim 1 have not been found as filed and thus are NEW MATTER. The closest component arrangements to these is present in claim 21 as filed but do not give written description of these arrangements. Claims 2-19, 21-39, 41, 51, and 52 also contain this NEW MATTER either directly or indirectly via dependence from a claim that explicitly contains it. This rejection is necessitated by amendment.

¹ Although they were uncertain as to the basis of the new matter rejection as it applied to claim 52, nevertheless Applicants have canceled claim 52 in a sincere effort to advance prosecution.

Christine L. Brakel et al. Serial No. 08/479,999 Filed: June 28, 1994

Page 9 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

As indicated in their opening remarks above, Applicants have restored the originally disclosed and claimed components (MN₃M, B(N)_xM and M(N)_xB) into the claims at hand.

In view of the above claim language and foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection for new matter.

The First Rejection Under 35 U.S.C. §102(b)

Claims 1, 2, 4, 8, 12-14, 19, and 42-50 are rejected under 35 U.S.C. §102(b) as being anticipated by Miller et al.(1985). In the Office Action (page 3), the Examiner stated:

This rejection is reiterated and maintained from the previous office action, mailed 1/4/99. Applicants argue that Miller et al. neither discloses nor suggests not fully modifying all of the internal phosphodiester linkages and is silent on RNase H sensitivity. This RNase H resistance argument is confusing in that instant claim 1, for example, lacks any mention of RNase H resistance or not. Only claims 44 and 49 as rejected hereinunder cite any RNase H practice and these claims, such as specifically claim 44 directs RNase H resistance to what is complexed with the compound of claim 42 and not the compound itself. This argument is thus non-persuasive as being directed to a limitation that is not in the claims under rejection.

The anticipation rejection is respectfully traversed.

As indicated in the opening remarks above, the present claims are directed to modified *RNase H resistant* nucleotide compounds, which distinguishes from Miller et al.

Accordingly, in light of the above claim amendments, Applicants respectfully request reconsideration and withdrawal of the first anticipation rejection.

Filed: June 28, 1994

Page 10 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

The Second Rejection Under 35 U.S.C. §102(b)

Claims 1-4, 12-14, and 42-50 stand rejected under 35 U.S.C. §102(b) as being anticipated by Stein et al.(1988). In the Office Action (page 4), the Examiner stated:

This rejection is reiterated and maintained from the previous office action, mailed 1/4/99. Applicants argue again as above regarding RNase H resistance. This argument has been responded to above and is equally applicable here and is reiterated here. Applicants then argue regarding partial internal modification that is not in Stein et al. This is non-persuasive as it is based on the NEW MATTER added to the instant claims. This rejection is reiterated in anticipation of removal of the NEW MATTER thus leaving the claims rejected as before.

The second anticipation rejection is respectfully traversed.

As indicated in the previous anticipation rejection, Applicants are now claiming modified RNase H resistant nucleotide compounds, which distinguishes their claimed invention from either of Miller et al. or the instant Stein et al.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the second anticipation rejection.

The Rejection Under 35 U.S.C. §103(a)

Claims 1-52 stand rejected under 35 U.S.C. §103 (a) as being unpatentable over Walder et al. (1988) in view of Miller et al. (4, 469, 863) and Inoue et al. (1988). In the Office Action (page 5), the Examiner stated:

This rejection is maintained and reiterated as given in the office action, mailed 1/4/99. Applicants argue based on the internal partial modification of the claimed compounds which has been noted above as being NEW MATTER. This rejection is reiterated in anticipation of removal of the NEW MATTER thus leaving the claims rejected as before.

Filed: June 28, 1994

Page 11 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

The obviousness rejection is respectfully traversed.

Applicants respectfully submit that the combination of cited documents would not have rendered their now claimed invention obvious to a person of ordinary skill in the art at the time their invention was made.

Reconsideration and withdrawal of the obviousness rejection is respectfully requested.

Submission of Art-Related Document

Applicants' attorney and his assistant are searching for any additional artrelated documents. Should any such document come to light, Applicants intend to submit them in a supplemental information disclosure statement as soon as an indication has been received that this application has been revived.

Submission of Consolidation Amendment

Applicants' attorney is consolidating all pending claims into a clean version. As soon as an indication has been received that the present application has been revived, the undersigned will submit a consolidation amendment including a clean version of the pending claims.

Filed: June 28, 1994

Page 12 [Amendment Under 37 C.F.R. §1.116 (In Response To The September 26, 2000 Office Action) - December 26, 2001]

SUMMARY AND CONCLUSIONS

Claims 1-51 as amended hereinabove are presented for further examination on the merits. Replacement claims 1, 18, 19, 21, 37, 41 and 51 have been entered above. Claim 52 has been canceled. No claim has been added by this paper.

This Amendment is accompanied by a Petition Under 37 C.F.R. §1.137(b) and authorization for the fee therefor. No other fee is believed due in connection with this Amendment, including any claim fee since one claim has been canceled and no claims have been added. If any other fee or fees are due, however, the Patent and Trademark Office is authorized to charge the amount of any such fee(s) to Deposit Account No. 05-1135, and to credit any overpayment thereto.

In view of the above discussion of the issues and amendments to the claims, Applicant respectfully submits that all of the instant claims are in allowable condition. Should it be deemed helpful or necessary, the Examiner is respectfully invited to telephone the undersigned at (212) 583-0100 to discuss the subject application.

Respectfully submitted,

Ronald C. Fedus

Registration No. 32,567 Attorney for Applicant

ENZO THERAPEUTICS, INC. c/o Enzo Biochem, Inc. 527 Madison Avenue, 9th Floor New York, New York 10017

Tel.: (212) 583-0100 Fax.: (212) 583-0150

CHRISTINE L. BRAKEL ET AL., U.S. PAT. APPL. SER. NO. 08/479,999 MARKED-UP VERSION OF THE AMENDED CLAIMS Exhibit A [Amendment Under 37 C.F.R. §1.116 -- December 26, 2001]

1. (Four Times Amended) A modified <u>RNase H resistant</u> nucleotide compound which includes at least one component selected from the group consisting of MN_3M , $[(N)_xM(N)_y, (N)_xM(N)_yM, B(N)_xM(N)_y and (N)_xM(N)_yB]$ <u>B(N)_xM and M(N)_xB</u> wherein

N is a phosphodiester-linked modified or unmodified 2'deoxynucleoside moiety; provided that at least one N is a phosphodiesterlinked unmodified 2'-deoxynucleoside moiety;

M is a moiety that confers endonuclease resistance on said component and that contains at least one modified or unmodified nucleic acid base;

B is a moiety that confers exonuclease resistance to the terminus to which it is attached; and

x is an integer of at least 2[; and y is an integer].

- 18. (Twice Amended) The modified nucleotide compound of claim 1 which includes at least one sequence of the formula [(N), M(N), B] M(N), B wherein B is modified or unmodified 2',3'-dideoxyribose nucleotide.
- 19. (Twice Amended) The modified nucleotide compound of claim 1 wherein [y] x is an integer selected from the group consisting of 2 or 2.

Filed: June 28, 1994

Page 2 [(Exhibit A to Amendment Under 37 C.F.R. §1.116 --

Marked-Up Version of Claims) - December 26, 2001]

21. (Four Times Amended) A method of inhibiting the function of an RNA, which comprises:

contacting said RNA, under conditions permissive of hybridization, with a modified RNase H resistant nucleotide compound which includes at least one complementary component selected from the group consisting of MN₃M, $[(N)_*M(N)_*, (N)_*M(N)_*M, B(N)_*M(N)_* and (N)_*M(N)_*B] \underline{B(N)_*M} \underline{and} \underline{M(N)_*B} \underline{B(N)_*M} \underline{M(N)_*B} \underline{B(N)_*M} \underline{M(N)_*B} \underline{B(N)_*M} \underline{M(N)_*B} \underline{B(N)_*M} \underline{M(N)_*B} \underline{M(N)_*B$

N is a phosphodiester-linked modified or unmodified 2'-deoxynucleoside moiety; provided that at least one N is a phosphodiester-linked unmodified 2'-deoxynucleoside moiety;

M is a moiety that confers endonuclease resistance on said component and that contains at least one modified or unmodified nucleic acid base;

B is a moiety that confers exonuclease resistance to the terminus to which it is attached; and

x is an integer of at least 2[; and y is an integer].

- 37. (Twice Amended) The method of claim 21 wherein the RNA is contacted with a compound which includes at least one sequence of the formula [(N), M(N), B] wherein B is modified or unmodified 2',3'-dideoxyribose nucleotide.
- 41. (Twice Amended) A method of treating a human or animal so as to inhibit the function of a target RNA therein which method comprises administering a therapeutically effective amount of a modified nucleotide compound so as to inhibit the function of the target RNA, which modified **RNase H resistant** nucleotide compound includes at least one component selected from the group consisting of

Filed: June 28, 1994

Page 3 ((Exhibit A to Amendment Under 37 C.F.R. §1.116 --

Marked-Up Version of Claims) - December 26, 2001]

MN₃M, $[(N)_*M(N)_*, (N)_*M(N)_*M, B(N)_*M(N)_* and (N)_*B]$ B(N)_{*}M and M(N)_{*}B wherein:

N is a phosphodiester-linked modified or unmodified 2'-deoxynucleoside moiety; provided that at least one N is a phosphodiester-linked unmodified 2'-deoxynucleoside moiety;

M is a moiety that confers endonuclease resistance on said component and that contains at least one modified or unmodified nucleic acid base;

B is a moiety that confers exonuclease resistance to the terminus to which it is attached; and

x is an integer of at least 2[; and y is an integer].

51. (Twice Amended) A modified nucleotide compound which comprises at least one component selected from the group consisting of MN₃M, $[(N)_xM(N)_y$, and $(N)_xM(N)_y$. B(N)_xM(N)_y and $(N)_xM(N)_y$. Wherein:

N is a phosphodiester-linked modified or unmodified 2'-deoxynucleoside moiety; provided that at least one N is a phosphodiester-linked unmodified 2'-deoxynucleoside moiety;

M is a moiety that confers endonuclease resistance on said component and that contains at least one modified or unmodified nucleic acid base;

B is a moiety that confers exonuclease resistance to the terminus to which it is attached; and

x is an integer of at least 2[; and y is an integer].

Enz-47(C2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Christine L. Brakel et al.

Serial No.: 08/479,999

Group Art Unit: 1631

Filed:

June 28, 1994

Examiner: Ardin H. Marschel, Ph.D.

Title: MODIFIED NUCLEOTIDE COMPOUNDS

(As Previously Amended)

FILED BY EXPRESS MAIL

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

NOTICE OF APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Sir:

Applicant(s) hereby appeal(s) to the Board of Patent Appeals and Interferences from the decision dated September 26, 2000 of the Primary Examiner, finally rejecting or obejeting to claims 1-52.

EXPRESS MAIL CERTIFICATE

"Express Mail" Label No. EL491424303US

Deposit Date

December 26, 2001

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and

Trailemarks, Wathington DC 20231.

DEC 26 2001

Ronald C. Fedus

Reg. No. 32,567

Date

Christine L. Brakel et al. Serial No.: 08/479,999 Filed: June 28, 1994 Page 2 (Notice of Appeal)

The items checked below are appropriate:

1.	X_	Appeal Fee of \$320.00
2.		Fee enclosed.
3.		Fee not required (e.g., Fee paid in prior appeal).
4.	X	Charge Fee to Deposit Account No. 05-1135.
		(A DUPLICATE COPY OF THIS SHEET IS ATTACHED.)
5.	X_	The Commissioner is hereby authorized to charge any additiona
		fees which may be required by this paper, or to credit any
		overpayment to Deposit Account No. 05-1135.

December 26, 2001 Date

Ronald C. Fedus Registration No. 32,567 Attorney for Applicants

Respectfully submitted,

ENZO THERAPEUTICS, INC. c/o ENZO BIOCHEM, INC. 527 MADISON AVENUE, 9TH FLOOR NEW YORK, NY 10022 TEL. (212) 583-0100

FACSIMILE: (212) 583-0150

Attorney's Docket No.: Enz-47(C2)